REMARKS

Claims 24-68 are pending in the application, claims 1-23 having been cancelled and claims 24-68 having been added by the above amendment. Support for the new claims can be found in original claims 1-7, 12, and 18 and in the specification at, e.g., page 4, lines 26-31; page 7, line 27, to page 8, line 3; page 9, line 23, to page 10, line 8; page 17, lines 30-35; page 18, lines 16-24; page 19, lines 16-35; page 20, line 10, to page 21, line 22; page 21, line 34, to page 22, line 20; and page 28, line 14, to page 29, line 7. No new matter has been added by these amendments.

Objections to the Specification

On page 2 of the Office Action, the Examiner objected to the specification's omission of the ATCC deposit numbers and the dates of deposit for the biological material. Applicants will amend the specification to insert the relevant deposit information when the ATCC deposit numbers and dates of deposit have been obtained.

Information Disclosure Statement

On page 2 of the Office Action, the Examiner stated that "[n]o papers could be found for the IDS of 2/14/02, other than the entry on the file wrapper that a supplemental IDS was submitted." It is applicants' understanding that the IDS to which the Examiner refers is the IDS filed on January 14, 2002. Copies of the IDS, form PTO-1449, and the references included in the IDS are enclosed with the present response.

35 U.S.C. §112, First Paragraph

On pages 3-4 of the Office Action, the Examiner stated that

> [t]he specification is objected to as failing to provide an adequate written description and enablement for practicing the claimed invention because the application contains at numerous pages (e.g., pages 7+ of the present specification) references to deposited biological material but only contains "ATCC ____". It is not readily apparent that the identical materials are reproducible from the instant application as to the genetic material and/or the encoded polypeptide nor to unspecified and/or allelic variants thereof. These

deposited materials are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the organism is not so obtainable or available, the requirement of 35 U.S.C. 112 may be satisfied by a deposit of the microorganisms/cells.

Claims 1-23 have been cancelled and new claims 24-68 have been added.

The Office Action does not identify any specific claims that are rejected under this heading. Original claim 2 is understood to have not been rejected, as the Examiner stated on page 8 of the Office Action that claim 2 would be allowable if rewritten in independent form including all of the limitations of the base claim an any intervening claims.

Applicants respectfully submit that the specification contains written description support for new claims 24-68 and enables a person of ordinary skill in the art to make and use the full scope of the presently claimed invention. Furthermore, no deposit of biological materials is necessary to satisfy either the written description requirement or the enablement requirement for the presently claimed nucleic acids.

All of the newly added claims recite specific nucleotide sequences (SEQ ID NO:1 or SEQ ID NO:3) or specific amino acid sequences (SEQ ID NO:2). The new claims encompass, for example, nucleic acids containing SEQ ID NO:1 or SEQ ID NO:3 or fragments or variants thereof, nucleic acids that hybridize to SEQ ID NO:3 under defined hybridization conditions, and nucleic acids that encode SEQ ID NO:2 or fragments or variants thereof. A person of ordinary skill in the biological arts, as of the filing date of the present application, would have been able to make and use the claimed nucleic acids without undue experimentation. For example, the nucleic acid of SEQ ID NO:1 can be readily prepared by a variety of means, including but not limited to: amplifying by PCR a cDNA prepared by reverse transcription of RNA derived from placental tissue (see, e.g., page 13, lines 22-25; and page 19, lines 1-16); or screening a cDNA library from placental tissue using a probe prepared from the sequence of SEQ ID NO:1 (see, e.g., page 13, lines 22-25; and page 19, lines 1-16). Fragments and variants of SEQ ID NO:1 can be prepared by well-known methods, including but not limited to: mutagenesis techniques such as site directed mutagenesis or PCR-mediated mutagenesis (see, e.g., page 22, lines 5-35); and standard automated DNA synthetic techniques (see, e.g., page 19, lines 1-16). Accordingly, the

claimed nucleic acids can be obtained without undue experimentation and without resort to deposited biological materials.

In addition to enabling the practice of the claimed invention, the specification also conveys to a person skilled in the art that the inventor had possession of the claimed subject matter as of the filing date of the present application. The claims provide a precise definition of the invention by structure, as is required for an adequate written description of a nucleic acid molecule. *Regents of the University of California v. Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). The recitation of specific nucleotide or amino acid sequences in the claims allows the skilled artisan to envision the full scope of the specific structures encompassed by the claims. Accordingly, a person of ordinary skill in the art would understand applicants to have been in possession of the claimed nucleic acids at the time the application was filed.

As detailed herein, the claimed nucleic acids are clearly amenable to written description and are not unique biological materials that cannot be duplicated. Accordingly, no deposit of biological materials is required to satisfy the enablement and/or written description requirements. In light of these comments and the claim amendments, applicants request that the Examiner withdraw the rejections.

35 U.S.C. §112, First Paragraph (Written Description)

On page 4 of the Office Action, the Examiner rejected claim 12 as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time of filing of the application. According to the Examiner, claim 12 lacked written description support for the reasons provided in the preceding 35 USC § 112, paragraph 1 rejection (at pages 3-4 of the Office Action).

Original claim 12 was directed to a method of producing a polypeptide. Claim 12 has been cancelled, thereby rendering its rejection moot. New claim 67 is directed to a method of producing a polypeptide by culturing a host cell under conditions that allow for expression of a nucleic acid comprising a nucleotide sequence that encodes a polypeptide containing amino acid residues 1-88, 161-323, or 762-965 of SEQ ID NO:2. The recited amino acid sequences correspond to specific predicted functional regions of the CARD-12 polypeptide of SEQ ID

NO:2: the caspase recruitment domain (CARD); the nucleotide binding site (NBS); and the leucine rich repeat (LRR) domain. Polypeptides containing these specific regions are described in detail throughout the specification (see, e.g., page 14, lines 29-36; page 16, lines 1-4; and page 21, line 34, to page 22, line 4). As described in the response to the 35 USC § 112, paragraph 1 rejection above, the specific polypeptides encoded by the nucleic acids of the claimed invention are clearly amenable to written description, are not unique biological materials that cannot be duplicated, and therefore need not be deposited to satisfy the written description requirement. In light of these comments and the claim amendments, applicants request that the Examiner withdraw the rejection.

35 U.S.C. §112, First Paragraph (Enablement)

On pages 4-6 of the Office Action, the Examiner rejected claim 12 as allegedly not enabled. According to the Examiner,

> the specification, while being enabling for a method of producing a polypeptide of SEQ ID NO:2, does not reasonably provide enablement for producing a fragment of at least 15 residues nor for any item in c) in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with this claim as directed to any and all fragments and allelic variants.

Original claim 12 was directed to a method of producing a polypeptide. Claim 12 has been cancelled, thereby rendering its rejection moot. New claim 67 is directed to a method of producing a polypeptide by culturing a host cell under conditions that allow for expression of a nucleic acid comprising a nucleotide sequence that encodes a polypeptide containing amino acid residues 1-88, 161-323, or 762-965 of SEQ ID NO:2. As detailed above with respect to the written description rejection, the polypeptide produced by the method of claim 67 contains at least one of three specific predicted functional regions (CARD, NBS, and/or LRR domain) of the CARD-12 polypeptide of SEQ ID NO:2. Nucleic acids encoding the polypeptides produced by the method of claim 67 can be made by standard molecular biology techniques described in the specification, for example, at page 19, lines 1-35. Because polypeptides produced by the claimed method contain at least one of the predicted functional regions of a CARD-12 polypeptide, the polypeptides can be used, for example, to screen for compounds that bind to

CARD-12 and/or modulate a CARD-12 function. Accordingly, a person of ordinary skill in the art, as of the filing date of the present application, would have been able to carry out the method of new claim 67 with no undue experimentation. In light of these comments and the claim amendments, applicants request that the Examiner withdraw the rejection.

35 U.S.C. §102(a)

On page 6 of the Office Action, the Examiner rejected claims 1, 3-5, and 18 as allegedly anticipated by GenBank™ Accession No. AQ309404. According to the Examiner, GenBank™ Accession No. AQ309404 "is deemed anticipatory for the claimed subject matter of claim 1b, 1d and 1e because the complement of nucleotides 2-552 is 100% identical to nucleotides 1462-2012 of SEQ ID NO:1."

Claims 1, 3-5, and 18 have been cancelled, thereby rendering their rejection moot. New claims 24-68 have been added, none of which is anticipated by GenBank™ Accession No. AQ309404. For example, new claim 42 is directed to an isolated nucleic acid that encodes a polypeptide comprising at least 200 contiguous amino acids of SEQ ID NO:2. The nucleotide sequence of GenBank™ Accession No. AQ309404 does not encode a polypeptide that contains at least 200 contiguous amino acids of SEQ ID NO:2. In another example, new claim 58 is directed to isolated nucleic acid comprising at least 600 contiguous nucleotides of the nucleotide sequence of SEQ ID NO:1. The nucleotide sequence of GenBank™ Accession No. AQ309404 does not contain at least 600 contiguous nucleotides of SEQ ID NO:1. In light of these comments and the claim amendments, applicants request that the Examiner withdraw the rejection.

35 U.S.C. §102(b)

On pages 6-7 of the Office Action, the Examiner rejected claims 1, 3-5, and 18 as allegedly anticipated by GenBank™ Accession No. AQ112439. According to the Examiner, GenBank™ Accession No. AQ112439 "is deemed anticipatory for the claimed subject matter of claim 1b, 1d and 1e because nucleotides 485-630 are 100% identical to nucleotides 2349-2494 of SEQ ID NO:3."

Claims 1, 3-5, and 18 have been cancelled, thereby rendering their rejection moot. New claims 24-68 have been added, none of which is anticipated by GenBank™ Accession No. AQ112439. Similar to the discussion above with respect to the 35 USC § 102(a) rejection, the nucleotide sequence of GenBank™ Accession No. AQ309404 does not, for example: encode a polypeptide that contains at least 200 contiguous amino acids of SEQ ID NO:2 (see new claim 42); or contain at least 600 contiguous nucleotides of SEQ ID NO:1 (see new claim 58). In light of these comments and the claim amendments, applicants request that the Examiner withdraw the rejection.

35 U.S.C. §103(a)

On page 7 of the Office Action, the Examiner rejected claims 5-7 as allegedly unpatentable over GenBank™ Accession No. AQ309404 or GenBank™ Accession No. AQ112439. According to the Examiner, "[i]t is not clear that the host cells are non-human mammalian host cells. It, however, is a design choice to use any cell type for propagation of a vector."

Original "host cell" claims 5-7 have been cancelled, thereby rendering their rejection moot. As detailed above with respect to the anticipation rejections, neither GenBank™ Accession No. AQ309404 nor GenBank™ Accession No. AQ112439 anticipates any of new claims 24-68. New claims 65 and 66 are specifically directed to host cells comprising the vector of claim 64 (a vector containing the nucleic acid of new claim 24). The cited references do not provide a suggestion or a motivation that would lead a skilled artisan to modify a nucleotide sequence described therein to arrive at a nucleic acid of the presently claimed invention. Furthermore, the references do not provide the requisite suggestion or motivation to create a vector or host cell containing the nucleic acid of new claim 24. In light of these comments and the claim amendments, applicants request that the Examiner withdraw the rejection.

CONCLUSIONS

Applicants submit that all grounds for rejection have been overcome, and that all claims are now in condition for allowance, which action is requested.

Attached is a marked-up version of the changes being made by the current amendments. The attached pages are captioned "Version with Markings to Show Changes Made."

Enclosed is a check for excess claims fees. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 07334-136001.

Respectfully submitted,

Date: August 9, 2002

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Version with Markings to Show Changes Made

In the Claims:

Claims 1-23 have been cancelled without prejudice.